

STANDARD OPERATING PROCEDURES (SOPs) FOR CLINICAL RESEARCH	Version 05/2012
TITLE: Protocol Feasibility Assessment	
Center for Clinical Research and Technology Office of Research Compliance and Education	1 of 2

1. PURPOSE:

This Standard Operating Procedure (SOP) describes the standards for fulfilling the scientific, regulatory, medical, and ethical requirements for assessing the feasibility of implementing a protocol at University Hospitals.

2. SCOPE:

This SOP will provide instruction and set minimum standards regarding the process for assessing protocol feasibility for all departments within University Hospitals involved in the conduct of research. This SOP is not intended to supersede existing systematic processes for assessing protocol feasibility by a department but is intended to set a minimum standard.

3. RESPONSIBLE INDIVIDUALS:

This SOP applies to all Investigators desiring to conduct a research study at University Hospitals. In addition, the Department Review Committee and/or Department Chair or designee is also charged with ensuring that this review is complete and thorough. It is encouraged that other individuals who may be involved in the execution of the protocol are included in the feasibility assessment.

4. DEFINITIONS:

Please reference the Glossary for complete definitions of terms found in this SOP.

5. POLICY STATEMENT:

All research protocols must be reviewed for scientific merit and ethical standards consistent with local, state and federal requirements and must be consistent with UH IRB Policy, [Department Review of Protocols](#)

6. PROCEDURES:

For an investigator whose respective department does not already have an established process for systematically assessing protocol feasibility, the following procedures must be executed:

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The Principal Investigator (PI) will review the protocol to determine whether: 1) the protocol meets scientific and ethical merit; 2) the protocol is financially feasible; and 3) adequate resources are available to conduct the study.

As the PI reviews the protocol, he/she should systematically consider and evaluate the protocol and document the evaluation. The systematic approach can be achieved by using any or all of the tools referenced in this SOP under Forms and Attachments (Examples: Protocol Feasibility Checklist, or Research Vetting Ticket) or other protocol feasibility assessment tools or processes. Regardless of the evaluation process (i.e. following established department procedures or investigator assessment as noted above) or tools used for the assessment, the investigator must maintain documentation of this review.

The PI will clarify any questions with the Sponsor (if applicable).

If the PI finds that the protocol is feasible, the protocol as well as the documented assessment of feasibility is to be forwarded to the Department Review Committee and/or Department Chair for review. (See UH IRB Policy, Department Review of Protocols).


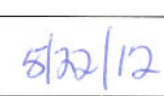

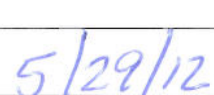
7. REFERENCES

UH IRB Policy, **Department Review of Protocols** (rev 5.2007)

8. FORMS OR ATTACHMENTS

Protocol Feasibility Checklist
Research Vetting Ticket

APPROVALS

	
Clinical Research Manager	Date
	
Vice President, Research and Technology	Date

Checklist for Feasibility Assessment of Research Protocol

Review Tool

Feasibility Reviewer:

Sponsor:

Study Title:

Date of Review:

Funding Source:

A. Sponsor/Clinical Research Organization

	Yes	No	Unkn	N/A
Has the confidentiality agreement (CDA) been signed by all parties?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has previous experience with this Sponsor/CRO been satisfactory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If no previous experience with this Sponsor/CRO, has the reputation been checked with colleagues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has a draft of the contract been received?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If the contract has been received, has it been forwarded for legal review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments:				

B. Population

	Yes	No	Unkn	N/A
Do you have access to the right participant population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are these targeted participants your patients?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How many patients do you see with this diagnosis that you can potentially enroll in one month?	Number: _____			
Is there a plan in place for identifying potential participants? (If yes consider noting under additional comments section)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will funding source be providing funding for recruitment & advertising?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the proposed enrollment goal realistic?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What is the screen failure ratio _____ was this calculated in enrollment #	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the enrollment period realistic for this site?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are inclusion/exclusion criteria so restrictive that recruitment will be low or very time consuming? Explain:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do any current studies or studies under consideration at your site or in the community compete for the same patient population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are vulnerable populations involved (children, impaired adults with special consent issues, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you expect a significant number of adverse events?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments:				

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Review Tool

C. Protocol

	Yes	No	Unkn	N/A
Is the protocol well designed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the protocol ethical?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is this study desirable to do from a scientific standpoint?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a benefit to the potential participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a risk to the potential participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the protocol in final form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is a draft consent form provided by the sponsor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are copies of the Case Report Forms/Data Forms available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are the Case Report Forms/Data Forms complex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a large number of Case Report Forms per subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the data required typically documented routinely in the medical record?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If not collected as standard of care, has the impact of this on resources been considered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is necessary equipment available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If special equipment is needed, will the sponsor provide it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will coordination with other departments/services be required for study visits or procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Can other services (e.g., lab, radiology) meet the protocol requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the study unusually long in duration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are participant compliance problems likely?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will it be necessary to monitor subjects' compliance with time-consuming phone calls or other forms of communication?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are drug or device storage/accountability requirements complicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments:				

D. Procedures

	Yes	No	Unkn	N/A
Do procedures conflict with current standard of care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is physician credentialed to perform required study procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are procedures frequent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are procedures difficult?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are procedures painful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are procedures inconvenient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are subject diaries used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If subject diaries are used, does this require staff time for transcription or interpretation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the dosing schedule complex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are study visits complex, presenting possible scheduling difficulties?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Checklist for Feasibility Assessment of Research Protocol

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Additional Comments:

E. Staff

	Yes	No	Unkn	N/A
Does the investigator possess the qualification to oversee this study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the investigator possess the time to oversee this study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there research staff in place to coordinate the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will this study impact the physician office/clinic? If yes, explain:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will this study require after hours or on call staffing? If yes, explain:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are additional specialists needed? If yes, please list:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If an inpatient study, will floor staff need to be involved?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will ancillary departments/specialties be impacted by this study (i.e. surgery, cath lab, radiology, lab, pharmacy, neurology)? If yes, consider actual impact on staff operations of dept. and seek appropriate input.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If needed, is training available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments:				

F. Financial Impact

	Yes	No	Unkn	N/A
Does funding source's preliminary budget appear adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If funding source agrees to pay for "evaluable" subjects, is the definition of evaluable subject clear and acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will the funding source agree to pay for the coverage analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If the study is cancelled prior to enrollment, will the funding source pay for pre-study activities (IRB submission, meetings, chart reviews)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will the funding source pay for events that are difficult to budget for in advance, such as protocol amendments (consent form revisions), reconsenting subjects, unanticipated monitoring visits, audits, unexpectedly high number of SAE's?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there reimbursement and/or insurance issues to consider? If yes, explain:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Will the sponsor pay for an adequate number of screen failures (especially important for difficult protocols)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will the proposed payment schedule allow adequate upfront payment and payments paced according to work required by the protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will sponsor pay for record retention?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will sponsor pay for informed consent translations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments:				

G. General

	Yes	No	Unkn	N/A
Is adequate clinic and office or research unit space available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the sponsor expect this study to be audited by the FDA? (FDA audits take time)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has a project timeline been established? If yes, what is the targeted start date:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What will the sponsor's monitor frequency be? _____ Are you able to meet these needs? (Frequent visits will consume staff time but may help to minimize the number of data queries).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will the monitor need to meet with the PI at every visit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has there been a benefit identified for doing the study? If yes, specify all that apply:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Access to new technology/treatment options to patients				
<input type="checkbox"/> Potential for authorship				
<input type="checkbox"/> Good research question				
<input type="checkbox"/> Access to other studies by involvement with this study				
<input type="checkbox"/> Exposure				
<input type="checkbox"/> Interest in working with this study group/sponsor				
<input type="checkbox"/> Unknown				
<input type="checkbox"/> Other:				
Additional Comments:				

Recommendation:

☐ Yes, move to the next step
 ☐ No, do not pursue at this time

Research Vetting Ticket

Principal Investigator _____	Name of Trial _____
Sponsor _____	Phase _____
Enrollment Goal Per Site _____	Total Enrollment For Trial _____
Number of Sites _____	Global Enrollment State Date _____
Estimated Enrollment Start Date _____	Estimated Enrollment End Date _____

	1	2	3	Score	Weight	Total
I. Feasibility			Total:			
Competing Trials	3+ competing trials active or in the pipeline over the next 6 months	1-2 competing trials active or in the pipeline over the next 6 months	0 competing trials active or in the pipeline over the next 6 months		.11	
Ease of Enrollment (Pt Population Available and Timeframe)	Less than 6 months to enroll patients	6-12 month timeframe to enroll patients	Over 1 year to enroll patients		.11	
Expected Patient Total Enrollment	Expected to reach less than 50% of site total enrollment	Expected to reach 50%-75% of site total enrollment	Expected to reach greater than 75% of total site enrollment		.12	
II. Academic Merit			Total:			
Degree of Innovation/Scientific Merit	Less innovative (e.g., Phase 3 & 4)	Potentially Innovative (e.g., Phase 2 & 3)	Highly Innovative (e.g., Phase 1 & 2)		.10	
Research Prestige	Global pharma trial with multiple sites	Limited site global pharma trial OR Investigator initiated trial from another site, including NIH	Investigator-initiated trial		.10	
Academic Impact	Little chance of publication/authorship	Likely to be listed as an author	Will be listed as first or last author		.12	
III. Funding			Total:			
Funding Source	Department Funded (No external support)	Industry Funded/ Foundation Funded	Federally or Peer Reviewed Funded		.10	
Projected Funding	Unfunded to a projected significant loss	Partially funded project	Fully funded project		.12	
Resources Available	No	Partial	Yes		.12	
TOTAL					1.0	

Please note: If the average score of all reviewers is below ____ then it is suggested to not participate in the clinical study. If the score is ____ or above than it is suggested to proceed in participating in this clinical study.

Accept or Reject Study: _____

Reviewed By: _____

Review Date: _____